

Notice of Allowability

Application No.

10/625,307

Examiner

Phillip Gambel

Applicant(s)

THOMPSON ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/29/07, 9/21/07.
2. ☒ The allowed claim(s) is/are 40-58, 63 renumbered 1-20.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☒ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: certified copies required / see Office Action.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Art Unit: 1644

DETAILED ACTION

1. Applicant's amendment, filed has been entered.
Claims 1-39 have been canceled.
Claims 40 – 63 have been added.

EXAMINER'S AMENDMENT

2. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.
3. Authorization for this Examiner's Amendment was given in a telephone interview with David Clough on September 21, 2007.
4. The Claims have been amended as attached.
5. The title has been replaced with the following:
-- HUMAN ANTIBODIES SPECIFIC FOR TGF β 2 -- .

REASONS FOR ALLOWANCE

6. The following is an Examiner's Statement of Reasons for Allowance:

Upon consideration of the Examiner's Amendment herein, which limits the claims to TGF β 2-specific antibodies comprising the 6H1-, 11E6-, Gold 11-, 1-G2-, 1-H6-, 6B1-, 6A5-, 11E6, 14F12-specific variable domains, the previous rejections under 35 U.S.C. 112, first paragraph, enablement, 35 U.S.C. § 102(b), 35 U.S.C. § 102(e), 35 U.S.C. § 103(a) and judicially created doctrine of obviousness-type double patenting.

Further, claims drawn to the TGF β 2-specific antibodies comprising the 6H1-, 11E6-, Gold 11-, 1-G2-, 1-H6-, 6B1-, 6A5-, 11E6, 14F12-specific variable domains appear to be free of the prior art. Accordingly the claims of this application are deemed allowable.

Art Unit: 1644

EXAMINER'S COMMENTS

7. In contrast to the indication on the PTOL-326, mailed 01/31/2007, applicant's priority documents were not found in USSN 09/054,847.

Applicant's provision of copies of the relevant priority documents via fax on 09/13/2007 has been much appreciated by the examiner.

Therefore, acknowledgment is made of applicant's claim for foreign priority based on an applications filed in the United Kingdom on 10/06/1995 and 01/19/1996. It is noted, however, that applicant has not filed certified copies of the United Kingdom 9520486.3 and the United Kingdom 9601081.4 applications as required by 35 U.S.C. 119(b).

The examiner apologizes for any inconvenience to applicant in this matter.

8. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
September 24, 2007



1644

U.S. Appln. No. 10/625,307
Filed: July 23, 2003

1.-39. (Canceled)

40. (Currently amended) An isolated antibody or antibody fragment thereof comprising an antibody-antigen binding domain of a human antibody specific for TGF β isoform TGF β 2, said antibody-antigen binding domain comprising;

- (a) a VH domain selected from the group consisting of the 6H1 VH domain of which the amino acid sequence is shown in Figure 2(a)(i) (SEQ ID NO: 6), the 11E6 VH domain of which the amino acid sequence is shown in Figure 2(a)(ii) (SEQ ID NO: 37), the Gold 11-VH domain of which the amino acid sequence is shown in Figure 2(a)(iii) (SEQ ID NO: 116), the 1-G2 VH domain of which the amino acid sequence is shown in Figure 2(a)(v) (SEQ ID NO: 120) and the 1-H6 VH domain of which the amino acid sequence is shown in Figure 2(a)(vi) (SEQ ID NO: 122); and
- (b) a VL domain selected from the group consisting of the 6B1 VL domain of which the amino acid sequence is shown in Fig 2(b)(iii) (SEQ ID NO:43), the 6H1 VL domain of which the amino acid sequence is shown in Fig 2(b)(i) (SEQ ID NO: 39), the 6A5 VL domain of which the amino acid sequence is shown in Fig 2(b)(ii) (SEQ ID NO:41), the 11E6 VL domain of which the amino acid sequence is shown in Fig 2(b)(iv) (SEQ ID NO:45), the 14F12 VL domain of which the amino acid sequence is shown in Fig 2(b)(v) (SEQ ID NO:47) and the 6H1 VL domain of which the amino acid sequence is shown in Fig 2(b)(vi) (SEQ ID NO:124).

41. (Previously presented) The antibody or antibody fragment thereof according to claim 40 which is in the form of scFv.

42. (Previously presented) The antibody or antibody fragment thereof according to claim 40 which is in the form of a whole antibody.

1644

U.S. Appln. No. 10/625,307
Filed: July 23, 2003

43. (Currently amended) An isolated antibody or antibody fragment thereof comprising an antibody-antigen binding domain of a human antibody specific for TGF β isoform TGF β 2, said antibody-antigen binding domain comprising;

- (a) a VH domain comprising the 6H1 VH domain CDRs shown in Figure 19(i), wherein VH CDR1 has the amino acid sequence set forth in SEQ ID NO: 126, VH CDR2 has the amino acid sequence set forth in SEQ ID NO: 127 and VH CDR3 has the amino acid sequence set forth in SEQ ID NO: 128, and
- (b) a VL domain comprising VL domain CDRs selected from the group consisting of:
 - (i) the 6B1 VL domain CDRs shown in Figure 19(ii), wherein VL CDR1 has the amino acid sequence set forth in SEQ ID NO: 129, VL CDR2 has the amino acid sequence set forth in SEQ ID NO: 130 and VH CDR3 has the amino acid sequence set forth in SEQ ID NO: 131,
 - (ii) the 6A5 VL domain CDRs shown in Figure 19(iii), wherein VL CDR1 has the amino acid sequence set forth in SEQ ID NO: 132, VL CDR2 has the amino acid sequence set forth in SEQ ID NO: 133, and VH CDR3 has the amino acid sequence set forth in SEQ ID NO: 134, and
 - (iii) the 6H1 VL CDRs shown in Figure 19(iv), wherein VL CDR1 has the amino acid sequence set forth in SEQ ID NO: 135, VL CDR2 has the amino acid sequence set forth in SEQ ID NO: 136, and VH CDR3 has the amino acid sequence set forth in SEQ ID NO: 137.

44. (Previously presented) The antibody or antibody fragment thereof according to claim 43 which is in the form of scFv.

45. (Previously presented) The antibody or antibody fragment thereof according to claim 43 which is in the form of a whole antibody.

46. (Previously presented) The antibody or antibody fragment thereof according to claim 43 wherein the VH domain is the 6H1 VH domain of which the amino acid sequence is shown in Figure 2(a)(i) (SEQ ID NO: 6).

47. (Previously presented) The antibody or antibody fragment thereof according to claim 46 which is in the form of scFv.

48. (Previously presented) The antibody or antibody fragment thereof according to claim 46 which is in the form of a whole antibody.

49. (Previously presented) The antibody or antibody fragment thereof according to claim 46 wherein the VL domain is selected from the 6B1 VL domain, of which the amino acid sequence is shown in Figure 2(b)(iii) (SEQ ID NO: 43), the 6H1 VL domain, of which the amino acid sequence is shown in Figure 2(b)(i) (SEQ ID NO: 124), and the 6A5 VL domain, of which the amino acid sequence is shown in Figure 2(b)(ii) (SEQ ID NO: 41).

50. (Previously presented) The antibody or antibody fragment thereof according to claim 49 which is in the form of scFv.

51. (Previously presented) The antibody or antibody fragment thereof according to claim 49 which is in the form of a whole antibody.

52. (Currently amended) An isolated antibody or antibody fragment thereof comprising an antibody-antigen binding domain of a human antibody specific for TGF β isoform TGF β 2, said antibody-antigen binding domain comprising;

- (a) a VH domain comprising the 6H1 VH domain CDRs shown in Figure 19(i), wherein VH CDR1 has the amino acid sequence set forth in SEQ ID NO: 126, VH CDR2 has the amino acid sequence set forth in SEQ ID NO: 127 and VH CDR3 has the amino acid sequence set forth in SEQ ID NO: 128, and
- (b) a VL domain comprising the 6B1 VL domain CDRs shown in Figure 19(ii), wherein VL CDR1 has the amino acid sequence set forth in SEQ ID NO: 129, VL CDR2 has the amino acid sequence set forth in SEQ ID NO: 130 and VH CDR3 has the amino acid sequence set forth in SEQ ID NO: 131.

53. (Previously presented) The antibody or antibody fragment thereof according to claim 52 which is in the form of scFv.

54. (Previously presented) The antibody or antibody fragment thereof according to claim 52 which is in the form of a whole antibody.

55. (Currently amended) An isolated antibody or antibody fragment thereof comprising an antibody-antigen binding domain of a human antibody specific for TGF β isoform TGF β 2, said antibody-antigen binding domain comprising the VH domain 6H1 VH of which the amino acid sequence is shown in Figure 2(a)(i) (SEQ ID NO: 6) and the VL domain 6B1 VL, of which the amino acid sequence is shown in Figure 2(b) (iii) (SEQ ID NO: 43).

56. (Previously presented) The antibody or antibody fragment thereof according to claim 55 which is in the form of scFv.

57. (Previously presented) The antibody or antibody fragment thereof according to claim 55 which is in the form of a whole antibody.

58. (Previously presented) A composition which comprises an antibody or antibody fragment thereof as in any one of claims 40, 43, 46, 49, 52 or 55 and an excipient.

59. (Canceled).

60. (Canceled).

61. (Canceled).

62. (Canceled).

63. (Previously presented) A pharmaceutical composition comprising an antibody or antibody fragment thereof as in any one of claims 40, 43, 46, 49, 52 or 55 and a pharmaceutically acceptable excipient